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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,742	12/29/2003	Mark Tawa	TPI-2900C3XC2	2066

23557 7590 07/29/2009

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
07/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/747,742	TAWA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,26-29 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 26-29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 31 Mar 2009, in which claim 7 is amended to change the scope and breadth of the claim.

This application is a domestic application, filed 29 Dec 2003; and claims benefit of 60/486,713 07/11/2003 and claims benefit of 60/459,501 04/01/2003 and claims benefit of 60/456,608 03/21/2003 and claims benefit of 60/456,027 03/18/2003 and claims benefit of 60/441,335 01/21/2003 and claims benefit of 60/437,516 12/30/2002 and is a continuation in part of 10/601,092 06/20/2003 abandoned which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and is a CIP of PCT/US03/19574 06/20/2003 which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and said 10/601,092 06/20/2003 claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/428,515 11/22/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003. This application 10/747,742 is a CIP of PCT/US03/19574 06/20/2003 which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002

and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 This application 10/747,742 is a CIP of PCT/US03/41273 12/24/2003 which is a CIP of 10/601,092 06/20/2003 ABN which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and said PCT/US03/41273 12/24/2003 is a CIP of 10/660,202 09/11/2003 which is a CIP of PCT/US03/27772 09/04/2003 which is a CIP of 10/378,956 03/03/2003 which claims benefit of 60/360,768 03/01/2002 and said PCT/US03/27772 09/04/2003 claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003 and said 10/660,202 09/11/2003 is a CIP of 10/637,829 08/08/2003 which is a DIV of 10/295,995 11/18/2002 PAT 6,699,840 and said 10/295,995 is a CON of 10/232,589 09/03/2002 PAT 6,559,293 which claims benefit of 60/406,974 08/30/2002 and claims benefit of 60/380,288 05/15/2002 and claims benefit of 60/356,764 02/15/2002 and said 10/660,202 is a CIP of 10/449,307 05/30/2003 PAT 7,078,526 which claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/444,315 01/31/2003 and claims benefit of 60/439,282 01/10/2003 and claims benefit of 60/384,152 05/31/2002 and said 10/660,202 is a CIP of 10/601,092 06/20/2003 ABN and claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003.

Claims 7, 26-29 and 32 are pending in the current application.

As detailed in the Office Action mailed 02 Jan 2009, the filing date of the instant claims is deemed to be the filing date of 60/437,516, 30 Dec 2002. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Rejections Withdrawn

Applicant's Amendment, filed 31 Mar 2009, with respect to claims 7, 26-29 and 32 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been fully considered and is persuasive, as amended claim 7 does not recite a composition comprising a form of a propylene glycol solvate of celecoxib that is characterized by peaks that are PXRD artifacts.

This rejection has been **withdrawn**.

The following are modified grounds of rejection necessitated by Applicant's Amendment, filed 31 Mar 2009, in which claim 7 is amended to change the scope and breadth of the claim by excluding the composition comprising a form of a propylene glycol solvate of celecoxib that is characterized by peaks that are PXRD artifacts. Claims 26-29 and 32 depend from claim 7 and incorporate all limitations therein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Amended Claims 7, 26-29 and 32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Upon further review of the claims as amended, the recitation of "a propylene glycol solvate of celecoxib sodium trihydrate characterized by a PXRD pattern..." and "a propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern..." are found to be indefinite for failing to particularly point out and distinctly claim the subject matter because the stoichiometric ratio of: (propylene glycol to celecoxib to sodium and 3 molecules of water); and the stoichiometric ratio of: (propylene glycol to celecoxib to sodium) is not defined. The definition of a solvate is "a substance formed by chemical union of two or more elements or ingredients in definite proportion by weight" (definition of solvate, The Free Dictionary, cited in PTO-892). While breadth is not indefiniteness, the specific recitation of "celecoxib sodium trihydrate" indicates a specific stoichiometric ratio is intended. In view of that recitation and the definition of a solvate as requiring ingredients in definite proportion, it is unclear what the scope of ratios for the propylene glycol solvate are intended to be embraced by the claim, therefore one of ordinary skill in the art would not reasonably apprised of the metes and bounds of the claim. The CAS Registry identifies the IUPAC names for the recited solvates in the instant application as Benzenesulfonamide, 4-[5-(4-

methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]-, sodium salt, compd. with 1,2-propanediol, hydrate (1:1:1:3) [CAS RN: 639010-40-5] and Benzenesulfonamide, 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]-, sodium salt, compd. with 1,2-propanediol (1:1:1) [CAS RN: 919287-67-5], therefore amendment to recite these stoichiometric ratios is a matter of nomenclature and would not constitute new matter.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended Claims 7, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Amended claims 7 recites "a propylene glycol solvate of celecoxib sodium trihydrate characterized by a PXRD pattern..." and "a propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern..." Claims 26-29 and 32 depend from claim 7 and incorporate all limitations therein. As recited above, it is unclear what scope of stoichiometric ratios for the propylene glycol solvates is recited in the claims.

The specification at paragraphs 144-146 of the corresponding PGPub US20070015841 describes the Benzenesulfonamide, 4-[5-(4-methylphenyl)-3-

(trifluoromethyl)-1H-pyrazol-1-yl]-, sodium salt, compd. with 1,2-propanediol (1:1:1). The specification at paragraphs 165-168 of the corresponding PGPub US20070015841 describes describes the Benzenesulfonamide, 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]-, sodium salt, compd. with 1,2-propanediol, hydrate (1:1:1:3). However, at paragraphs 146-147 of the corresponding PGPub, the specification discloses the PG solvate can give rise to distinct PXRD diffractograms. This variability in the PXRD diffractograms and the indefiniteness regarding the scope of stoichiometric ratios means the specification does not adequately describe the solvates other than the 1 celecoxib:1 sodium:1 propylene glycol having the recited PXRD patterns of Figures 2A, 2B, 2C or 2D or the 1 celecoxib:1 sodium:1 propylene glycol:3 hydrate having the recited PXRD pattern of Figure 21.

Dean (Analytical Chemistry Handbook, 1995, p10.24-10.26, cited in PTO-892) discloses that the x-ray pattern can be considered as a "fingerprint" of the compound (page 10.24, bottom of page). Dean discloses that each of the lines in the x-ray pattern is necessary to identify the component or if the crystal exists as a "mixture" such as if impurities are present (page 10.26, top of page).

The US Pharmacopia (US Pharmacopia #23, 1995, page 1843, cited in PTO-892) discloses that every polymorph and every solvate has its own characteristic X-ray pattern and that minor differences must be very carefully evaluated before it is concluded that the pattern characterizes a different solvate or polymorph (right column, paragraph 3).

Therefore, the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specific peaks may be characteristic of a solvate that has its own characteristic X-ray pattern, however the peaks must be very carefully evaluated before it is concluded that the pattern characterizes a different solvate or polymorph. In view of the disclosure in the specification that the PG solvate can give rise to distinct PXRD diffractograms, one individual peak does not appear to provide sufficient description to characterize a different solvate. The specification adequately describes the claimed subject matter of the 1 celecoxib:1 sodium:1 propylene glycol that gives the recited PXRD patterns of Figures 2A, 2B, 2C or 2D or the 1 celecoxib:1 sodium:1 propylene glycol:3 hydrate that gives the recited PXRD pattern of Figure 21.

Conclusion

No claim is found to be allowable.

Applicant's amendment, in which independent claim 7 is amended to change the scope and breadth of the claim by excluding the composition comprising a form of a propylene glycol solvate of celecoxib that is characterized by peaks that are PXRD artifacts, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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